BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/39, 17/22, 17/32 | A2

(11) International Publication Number: WO 95/02371

(43) International Publication Date: 26 January 1995 (26.01.95)

(21) International Application Number: PCT/GB94/01537

(22) International Filing Date: 15 July 1994 (15.07.94)

(30) Priority Data:
9314641.3 15 July 1993 (15.07.93) GB

(71)(72) Applicant and Inventor: SALIM, Aws, Shakir, Mustafa [IQ/GB]; 2 Dene Walk, Bishopbriggs, Glasgow G64 1LQ (GB).

(74) Agents: McCALLUM, William, Potter et al.; Cruikshank & Fairweather, 19 Royal Exchange Square, Glasgow G1 3AE (GB).

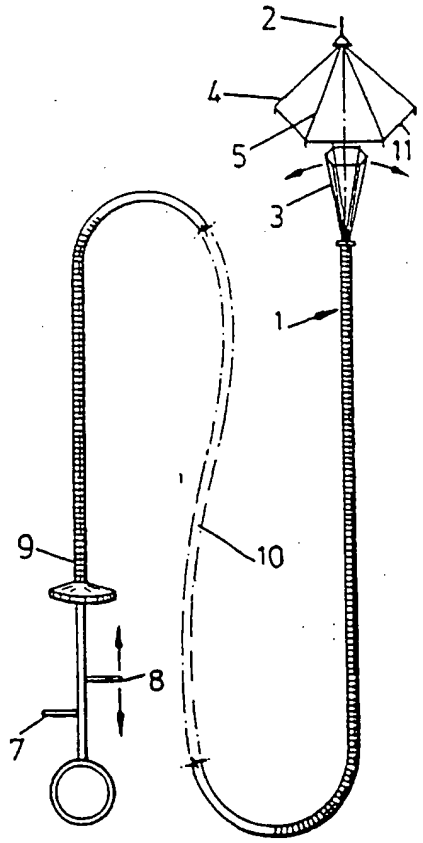
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, US, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD).

Published
Without international search report and to be republished upon receipt of that report.

(54) Title: RECTAL AND RECTOSIGMOID CANCER TUNNELLING UMBRELLA

(57) Abstract

The present invention provides a diathermy tunnelling umbrella device usable via the biopsy channel of an endoscope or through a proctoscope or a rigid sigmoidoscope. The device has remotely operable first and second opposed collapsible umbrella means with a diathermic distal end cutting and coagulating tip. A plurality of spaced apart diathermic cutting and coagulating spokes of the first umbrella means extend rearwardly from the tip towards the second umbrella means. The second umbrella means has a plurality of spaced apart diathermic cutting and coagulating spokes extending forwardly towards the first umbrella means. In use the device tip is advanced by diathermic cutting therewith into a growth with the umbrella means in substantially collapsed condition, at least one of the umbrella means is opened out by diathermic cutting of the spokes thereof generally radially outwardly into the growth, and the umbrella means manipulated by rotation and/or upward and downward movements for further diathermic cutting into said growth.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgyzstan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

RECTAL AND RECTOSIGMOID CANCER TUNNELLING UMBRELLA

The present invention relates to a diathermy umbrella device suitable for use in overcoming the emergency situation of large bowel obstruction caused by rectal or rectosigmoid tumours including carcinoma. The system employs diathermy cutting for tunnelling through and coring out the cancerous growth. Decompression of the bowel by this method avoids emergency surgery with its high morbidity and mortality rates and enables an elective operation to be carried out at a later date in a patient who has been properly investigated and prepared with a view to definitive surgery during the same hospital admission.

Fashioning a colostomy for the emergency presentation of large bowel obstruction caused by rectal or rectosigmoidal cancer does not represent the appropriate surgical approach necessary for dealing with the distended bowel and its plethoric part. Conversely, resectional surgery may be very challenging for the emergency surgeon who may be of limited experience in this type of surgery. It is now widely accepted that complete large bowel obstruction may lead to systemic problems thus producing a seriously ill patient which renders the management of the obstructed bowel only one facet of the treatment of a patient with multi-system failure. Consequently, overcoming the obstruction in a simple expeditious way which is least burdening to the patient represents a primary objective in the management of patient cases with large bowel obstruction. This would allow the valuable time necessary to improve the patient's general condition and then to investigate him/her with the potential for offering definitive surgery a few days later and during the same hospital admission.

It is an object of the present invention to avoid or minimize one or more of the above disadvantages and problems.

The present invention uses a diathermy umbrella device delivered endoscopically, using rigid or fibreoptic instruments, to the rectal or rectosigmoid part obstructed by tumours including benign and malignant neoplasms such as cancer. The device may be a single use disposable or reusable instrument. The basic principle of the diathermy current with regards to the invention is that of heating the device's tip and umbrellas (spokes and their connecting webs and or strings and rods) by high frequency electric current passing through their heating elements thus providing a cutting and/or coagulating effect.

The present invention provides a diathermy tunnelling umbrella device suitable for use via the biopsy channel of an endoscope or through a proctoscope or a rigid sigmoidoscope and having remotely operable first and second opposed collapsible umbrella means with a diathermic distal end cutting and coagulating tip, a plurality of spaced apart diathermic cutting and coagulating spokes of the first umbrella means extending rearwardly from said tip towards the second umbrella means which has a plurality of spaced apart diathermic cutting and coagulating spokes extending forwardly towards said first umbrella means, whereby in use the device tip is advanced by diathermic cutting therewith into a growth with the umbrella means in substantially collapsed condition, at least one of said umbrella means is opened out by diathermic cutting of the spokes thereof generally radially outwardly into the growth, and the umbrella means manipulated by rotation and/or

axially to and fro movements for further diathermic cutting into said growth.

Advantageously the spokes are interconnected by web means and/or diathermic cutting and coagulating flexible elongate connectors. Advantageously, the electric current provides electrocoagulation at both the tip and umbrella spokes and their connecting means to provide haemostasis if necessary. In addition this current may be unipolar or bipolar.

The tip of the umbrella device can tunnel through the growth using diathermy current, and once it has advanced for some distance, the proximal and/or distal umbrella is(are) opened up and their spokes used to core out the centre portion of the growth by forward or backward cutting manoeuvres with rotation to establish a complete tunnel though the tumour which relieves the emergency situation. This invention was initially developed in experimental animals and later successfully applied to the clinical situation.

The umbrella device may be manufactured in sizes suitable for use through the rigid proctoscope and sigmoidscope or the flexible scopes. The device can also be manufactured in sizes to suit veterinary uses. The present invention may be made in total or in part from metals such as steel, silver, aluminium, titanium etc, or alloys such as stainless steel. Certain parts may be made of plastics, silicones and/or rubber. Advantageously an antibiotic or antiseptic may be incorporated into any or all the parts of the device.

Further preferred features and advantages of the invention will appear from the following detailed description given by way of example of the use of an

umbrella device of the invention, with reference to the accompanying drawings in which:

Fig 1 is a general view of one embodiment a diathermy tunnelling umbrella device of the invention;
Fig.2 is a schematic representation of a suitable remote control opening means for one of the umbrellas of the device of Fig.1;
Fig.3 shows some different spoke end configurations;
Fig.4 shows some spoke edge configurations; and
Fig.5 shows some spoke surface formations

Patients who present with absolute constipation and abdominal distension produced by rectal or rectosigmoidal cancer are suitable for endoscopic tunnelling carried out as an emergency. Distension caused by faecal impaction should be excluded by two successive phosphate enemas one hour apart. Patients who present with peritonitis should proceed to a full laparotomy; otherwise endoscopic tunnelling can be offered to all emergency cases with large bowel obstruction as defined above. After physical examination and appropriate investigations including plain abdominal X-Rays, Sigmoidoscopic examination with or without biopsies and emergency barium enema (for diagnostic and therapeutic purposes), the patient is fasted and nasogastric aspiration with intravenous hydration commenced. A suitable intravenous antibiotic is given as prophylaxis then endoscopic examination using the rigid proctoscope, rigid sigmoidoscope and/or fibreoptic sigmoidoscope or colonoscope of the rectosigmoid lesion is carried out while the patient is under sedation by intravenous narcotic analgesics with or without benzodiazepines and midazolam. The procedure may also be carried out under general anaesthesic if this is indicated or preferable and in the left lateral

position. The obstructive lesion is located under direct vision and biopsied if necessary. The umbrella device is then passed through a rigid scope or the biopsy channel of a fibreoptic endoscope (not shown) and placed against the central portion of the lesion. The current is switched on and the tip 2 of umbrella 1 pushed into the lesion. Approximately one half to one centimetre lengths of the growth are cored out using the proximal and/or distal umbrellas 3, 4 by means of a process of opening up the umbrella 3, 4 and splaying out radially outwardly the main spokes 5 of the umbrella 3, 4 using the remote control operating handle means 7, 8 at the proximal end 9 of a respective elongate Bowden cable-type remote control operating link 10 and coring out (The main spokes 5 of the umbrellas 3, 4 are supported by a combination of links levers connected to a sliding collar in substantially similar manner to that used in conventional umbrellas and parasols used to provide shelter against sun or rain, and are not shown in detail herein). The simplest method is that of going through the growth with the tip 2 using cutting and coagulating current and coring off by the distal umbrella 4, twisting it every now and then or rotating it coupled with forward and backward movements to cut off tissues. Then when a full tunnel has been cored out, this is enlarged by opening further the distal umbrella 4 and withdrawing it, a procedure preferably supplemented by a rotating manoeuvre to extract the tissue that has been cut away. The procedure is continued until the obstruction is overcome and gas and faecal matter begin escaping. Obviously bleeding points can be electrocoagulated to achieve haemostasis using the tip of the instrument or either of the umbrellas. The endoscope and umbrella device are then taken out. When spontaneous passage of gas and faeces has ceased, a phosphate enema is administered. Thereafter no oral

intake restrictions are required and the patient is allowed up and about. The procedure of coring may be repeated the following day and 2 to 4 days later to ensure a suitable and adequate passage exists through the tumour. The patient is meanwhile prepared and investigated for definitive surgery to be carried out a few days later and during the same hospital admission. The investigations can now include colonoscopic and barium enema examinations through the tunnel in the growth.

Endoscopic tunnelling has been found during preliminary clinical investigations to be a simple, safe and effective procedure which offers advantages in the emergency management of large bowel obstruction caused by rectal or rectosigmoid tumours be they benign or malignant, particularly in the elderly and the very seriously ill patients. The procedure overcomes the obstruction thus directing efforts to improving the general condition of the patient. The technique is associated with no complications and permits patients to be properly investigated and prepared for definitive surgery a few days later and during the same hospital admission. Endoscopic tunnelling incurs the following gains in the overall management of emergency cases presenting with colonic obstruction caused by rectal or rectosigmoid tumours including cancer:

1. avoiding emergency surgery on an obstructed unprepared bowel
2. avoiding an operation by a person of limited experience
3. avoiding surgery on patients who are too ill on initial presentation
4. gaining valuable time properly to investigate the cause of the obstruction and for planning of the

correct surgical approach

5. allowing carrying out of a definitive procedure during the same hospital admission
6. adequate preparation of the patient for the definitive surgery.
7. shortening the overall hospital stay thus reducing costs and helping to ease the bed pressure situation.

The present invention provides a tunnelling umbrella for use to relieve large bowel obstruction caused by rectal or rectosigmoid tumours, including carcinoma. The device is introduced to the site of the blockage via the biopsy channel of a flexible scope or through the lumen of a rigid proctoscope or sigmoidoscope and consists of an externally controllable cutting and coagulating apparatus containing:

1. a diathermic tip
2. two sets of diathermic spokes in the form of back-to-back umbrellas which can be independently expanded or contracted to provide a variable cutting/coagulating radius.

In operation, the device is caused to enter the blockage by pushing the diathermic tip partially into it, with the umbrellas in the collapsed state. Diathermy currents are then applied to enable the tip to be advanced to the desired depth and to be appropriately positioned. The umbrellas are now progressively opened with rotation and backward/forward movement to core out a passageway through the blockage. When the passageway is sufficiently large, the device is retracted from the bowel with the upper (distal) umbrella still open allowing excised tissue to be removed. The procedure can be repeated the following day and 2 to 4 days later.

The tip and umbrellas are designed to deliver diathermy cutting and/or coagulating currents. Both monopolar and bipolar diathermy currents may be employed.

The device may be made of sizes suitable for use through the biopsy channel of flexible scopes (sigmoidoscope, colonoscope) or through the lumen of rigid scopes (proctoscope, sigmoidoscope) or for veterinary usage.

One or all parts of the catheter may be made of metals such as steel, silver, aluminium, titanium etc or their alloys such as stainless steel. One or more parts of the device may be made of plastic, rubber, silicones or their combinations. The most prefered substances to be employed are Teflon, Dacron, (Trade Names) latex, polyvinylchloride and biocompatible silicones. The materials and substances employed in the making of the tunnelling apparatus may be silver-impregnated or incorporate a silver-impregnated protective sheath. Similarly, bacterial resistant materials may be advantageously used in the manufacturing of all or part of the device. This includes the use of antibiotic bonded apparatus/device material.

The umbrella device may be manufactured for single use (disposable) or several uses (re-useable) after sterilization by ethylene oxide gas or autoclaving.

The overall length of the tunnelling umbrella head is generally in the range from 100mm to 2000mm, preferably 1500mm to 1600mm for use with the fibreoptic flexible scope (sigmoidoscope, colonoscope) and 100mm to 600mm for use with the rigid scopes (proctoscope, sigmoidoscope).

The outer diameter of the device's catheter ranges from

1.5mm to 30mm, preferably 1.8mm to 2.8mm for use with a fibreoptic scope and 2mm to 8mm for use with a rigid scope.

The outer sheath of the device's catheter may be made as a tube sheath type or coil sheath type. The tube sheath can be made to provide a highly flexible catheter sheath.

The tip of the device is generally a solid stiff structure, but, if desired, it can be made more or less flexible. The overall length is preferably from 2mm to 30mm, most preferably 5mm to 10mm. The tip may be in the shape of a needle or have a round bodied end. The needle can be pointed or bevelled having a diagonal slant of an angle ranging from 10° to 80°, preferably 30° to 45°.

The body of the device's tip may be cylindrical, faceted having 3 to 10 surfaces, serrated, saw-toothed or uneven with a roughened surface. Advantageously, the tip may be conical or frusto-conical having a base wider and larger than the end. The tip could also be in the shape of a corkscrew to facilitate tunnelling and as such could have from 1 to 15 turns.

The handle of the device is desirably formed and arranged so as to be substantially ergonomic and provide good grip and handling characteristics that enable the tip and the two umbrellas (with their electrical functions) to be independently and effectively applied. The handle generally carries a remote control mechanism for each of the two umbrellas that can be independently operated and may also carry the electrical connections for the active electrode besides the necessary switches to switch the electrical current on or off, regulate its intensity and determine whether it is cutting or

coagulating. The handle can range from 2cm to 20cm in length and 0.5cm to 10cm in width. It may be in the form of a disc, cylinder, sphere, triangle, square, rectangle or any other geometrical or non-geometrical shape. It can be in one or more parts e.g. it can be made in two halves. Advantageously, it can incorporate a sliding forward and backward movement mechanism. The handle may also include hinges. When made of many parts, each or all may be fixed or allow the movement of one part onto the other. The handle may incorporate from one to five finger accommodating bars, ridges, grooves, holes, rings or circular bonds. These may also be provided separately for each of the two umbrella controlling mechanisms if such mechanisms are located outside the main body of the handle. Any part of the handle may be solid or hollowed.

The umbrella operating mechanisms are preferably two independent means that allow each umbrella to be operated individually. Such mechanisms may be in the form of knobs, handles, rings, bars, ridges, switches, levers, buttons or any other suitable design that enables manual opening and closing of each of the two umbrellas separately. Optionally, the handle may incorporate two pistons that can be independently pushed backward and forward to open or close each of the umbrellas. These pistons may have a ring shaped, spherical, rounded, circular, discoid, T-shaped or any other suitable shaped handle for operating and remote controlling the umbrellas that may be fitted onto the rear or side of the handle.

Besides mounting the umbrellas' operating mechanisms, the handle can carry the electrical connections and/or deliver the electrical current from the active electrode to the two umbrellas and tip. As such, the handle may

incorporate one to ten electrical plugs or sockets which may be flush with the surface or project above it. These connecting points may be placed anywhere on the handle. Optionally all electric connections may be removed from the handle and incorporated directly into the main body of the catheter.

Each of the two umbrellas of the tunnelling device is preferably made from up of 2 to 12 spokes. The length of each spoke generally ranges from 3mm to 50mm, preferably 5mm to 15mm. The diameter, width or cross section generally ranges from 0.1mm to 5mm. The spokes are connected to the central axial support "pole" by hinges or welded onto it at on end. Alternatively the spokes may be cut out of an outer catheter sleeve which surrounds the central pole. The spokes open up radially around a central pole by mechanical displacement.

The spokes may be in the form of wires, blades or bars. The bars may be triangular, square, rectangular or of other polygonal section having from 5 to 12 surfaces in cross section or could have a rounded section. The wires, bars and blades may have serrated, roughened, spikey, notched, grater-like or saw-toothed surfaces to enable cutting into tissues while providing a firm grip or hold onto them. The wires may be spring coils or rods. The free end of each spoke may be pointed, bevelled, rounded, knob-shaped, L-shaped, T-shaped, spiral or any other suitable design to enable a better tissue grip for cutting and coagulating to be achieved.

Each umbrella may be made of the same type of spokes, whose surfaces may be similar or a combination of the types described above, or use different types of spokes with similar or different surfaces. The lengths of the spokes of each umbrella may be the same or different.

Similarily, the two umbrellas may be similar or different with regards to size, length, number and shape of spokes, including their lengths and surfaces.

The spokes of each umbrella may be connected together by one or more e.g. up to five webs, chains or other more or less flexible connectors.

The outer diameter of the collapsed umbrella is preferably from 1.5mm to 10mm, most preferably 1.5mm to 2.8mm for use with the fibreoptic flexible scopes. The diameter of umbrella when opened up is generally from 10mm to 40mm.

All the spokes within each umbrella can be arranged to deliver electrocoagulating and cutting diathermy currents.

Desirable each umbrella is individually and separately operable by remote control means built into the handle or attached to it. The device is delivered to the site of blockage under direct vision and with both umbrellas in the closed collapsed shape. The tip is placed in direct contact with the lesion and the current is switched on. The tip is advanced into the lesion; then the distal umbrella is slightly opened while the cutting current is switched on to enable the spokes to cut into the lesion; and the device is next rotated to core out some of the lesion. It is desirable that the whole coring out procedure be carried out strictly under direct vision. Thus, the tip of the device should not be pushed too much into the lesion at any one time, nor should the radially outward coring out be too generous. Sufficient coring out should desiarably though be carried out to enable correct guidance of the tip more deeply into the lesion as required. When gas begins to

escape indicating the creation of a tunnel through the blockage, the tip is pushed beyond the lesion to enable the distal umbrella to be opened up beyond the lesion, then the device is withdrawn with the cutting current still on to core out more of the lesion. The two umbrellas may be simultaneously or successively used to effect the most desirable coring out of the lesion which creates sufficient passageway that unblocks the rectum or rectosigmoid region. Since the umbrellas will cut the lesion or tumour electrically when opened up and will cut off the growth electrically when rotated around the central longitudinal axis of the device, a combination of forward and backward movements will enhance the electro cutting procedure aimed at achieving the best tunnelling effect. Bleeding points can be secured by electrocoagulation using the tip and/or the spokes of either or both umbrellas of the device. The procedure can be repeated several times until the obstruction is satisfactorily removed. With the two umbrellas provided, it is possible to achieve a high degree of control and selectivity in the extent and position (axially) of radial cutting carried out by using one or other or both with varying degrees of opening e.g. in order to improve vision before further advancing the device into the tissue.

The principles of surgical diathermy are well known in the art and further information is available from standard reference books such as "Encyclopedia of Medical Devices and Instrumentation" published by John Wiley & Sons, New York etc (1988) and other sources, and accordingly need not be described herein in detail.

Briefly diathermy operates by producing an alternating current with wavelengths generally in the radio frequency range. This current passes through the

patient's tissues from the active electrode, which may be of various shapes,to the indifferent or dispersive electrode, which is usually a metal or foil plate approximately 15 X 15cm in size. As this current passes through the tissues there is a heating effect beneath each electrode. The indifferent electrode has a large contact area and therefore heating is reduced to a minimum and is dissipated rapidly. The active electrode being small will concentrate heat in the tissues adjacent to it. The current intensity determines whether a coagulating, fulguration or electro-sectioning is produced.

The circuit of the diathermy machine being generally similar to that of a simple radio transmitter will generally oscillate at a frequency between 400kHz (Kilocycles) and 3MHz (megacycles). Oscillators used in earlier diathermy machines incorporating the standard spark - gap principle which provide a frequency of around 500kHz may be used. This would provide excellent coagulation but would cut only by increasing the intensity to a high - power output. Also, valve oscillators of a frequency range of up to 3MHz may be used. This can be in the form of two circuits: with a cutting circuit operated by a valve oscillator and the coagulating circuit operated by a spark-gap oscillator. Diathermy generators of power outputs up to 1 kW may conveniently be employed. The use of transistors as oscillators rather than valves is more advantageous.

The quality of coagulation or cutting generally depends on the wave form presented by the diathermy machine, with a smooth sine wave giving the desired cutting while an interrupted burst of current provides the desired coagulation depending on the frequency of these bursts and the length of the gap between each burst. The

spark-gap machine gives bursts of damped oscillation of a frequency of approximately 10kHz. When this interuption of current is superimposed on the sine wave oscillation, the coagulation quality is comparable to that of the spark-gap machine. In order to provide an adequate intensity of current the amplitude of each wave should be increased in portion to the length of each burst of current. Thus the doubled circuit may be dispensed with.

Blending the current may be provided by a twin-circuit diathermy where the blender switch brings both circuits into action at the same time with the result that the active electrode produces a cutting effect as well as a coagulating effect as it passes through the tissues. Conversely, a solid state transistorised diathermy machine can be used to provide a blended current from a single circuit by taking the setting halfway between the pure sine wave for cutting and repeated short bursts for coagulation. This provides the advantage of subjecting the patient to only the normal power output of a single circuit. Thus electro-sectioning can be provided by cutting with a valve or transistorised oscillator to ensure minimal surrounding tissue damage or cutting with a blended current if moderate degrees of surrounding coagulation is desirable.

The diathermy machine should normally be earthed to the floor to avoid build up of electrical potential which could discharge in the form of a spark of static electricity. It may be advantageous to monitor the contact of the plate electrode to patient by measuring the potential difference between the input and output leads.

The overall power output of the diathermy machine is

preferably restricted to from 400 to 500 kW.

The diathermy generator may conveniently be provided by valve oscillating machines, double - circuit spark and valve machines, transistorised solid state diathermies and spark-gap generators.

A foot pedal switch or finger switch may be used to activate the diathermy set, i.e. activating the operating electrode to start the diathermy.

To ensure that the plate is in electrical continuity with the diathermy generator, its cable is preferably designed to have an internal circuit so that if any point between the plate and the diathermy machine is disconnected then an alarm will sound which should also inactivate the circuit of the machine. This may not be necessary with earth-free circuits since the diathermy will be non-operated when the patient is not in contact with the indifferent electrode. Thus, earth-free circuits may also be used for the purposes of the present invention.

The electric connections to the diathermy machine may be placed on any part of the handle. The active electrode socket may be designed in any convenient way to enable the current to flow from the diathermy machine to the catheter tip and both umbrellas. This socket transmits the electric current from the machine directly to the tunnelling device. It may be flush flat with the handle surface or project above it. The active electrode may be plugged in, screwed in, clipped-on or fitted into the socket in any convenient way through one or more points of contact. The handle may have a finger switch to activate the diathermy set. Conversely this may be provided by a foot pedal. The indifferent electrode

plate is preferably stuck, strapped or attached in any way onto the patients lower limb, but other sites may also be used.

After the rigid or flexible scope has been introduced and the lesion or tumour assessed with or without biopsy, the tunnelling device is introduced into the rectum or rectosigmoid region and placed in direct contact with the lesion or tumour. The active electrode is connected to the device then the diathermy machine is switched on. The coagulating and cutting currents are generally set in the range from 20 to 90 A, preferably 30 to 60 A. During use the diathermy machine makes a noise which can be clearly heard to indicate it is working and the current is flowing. The coagulating and cutting currents are used as already described. Repeated sessions of tunnelling may be necessary to achieve the desired coring and tunnelling.

It will be understood that various modifications may be made to the above described embodiment without departing from the broadest scope on the present invention. Thus for example a wide variety of remote control operations handle mechanisms may be used including: systems with first and second relatively displacable finger rings or other finger engagement formations which may simply be relatively displacable longitudinally of the device, so as to provide a more or less direct longitudinal compression of the basket resulting in radial expansion, or may be relatively displacable in other dimensions e.g. by compressing or pulling laterally towards each other, conveniently against a return force exerted by resilient biasing means, spaced apart finger engagement portions and use one or more of links, levers, gears and other well known mechanisms for converting relative displacement into a suitable form for transmission to

the basket members. In addition hydraulic circuit means and/or electromechanical device may be used for transmitting required control movements to the basket in generally known maner. Conveniently the diathermic cutting and coagulating power supply control means are also provided on the handle means but this is not essential and they may be formed and arranged so as to be operable remotely from the handle means e.g. via a foot operated interface.

CLAIMS

1. A diathermy tunnelling umbrella device suitable for use via the biopsy channel of an endoscope or through a proctoscope or a rigid sigmoidoscope and having remotely operable first and second opposed collapsible umbrella means with a diathermic distal end cutting and coagulating tip, a plurality of spaced apart diathermic cutting and coagulating spokes of the first umbrella means extending rearwardly from said tip towards the second umbrella means which has a plurality of spaced apart diathermic cutting and coagulating spokes extending forwardly towards said first umbrella means, whereby in use the device tip is advanced by diathermic cutting therewith into a growth with the umbrella means in substantially collapsed condition, at least one of said umbrella means is opened out by diathermic cutting of the spokes thereof generally radially outwardly into the growth, and the umbrella means manipulated by rotation and/or axially to and fro movements for further diathermic cutting into said growth.

2. A device according to claim 1 wherein said spokes of each said umbrella means are at connected one end to a central axial support and are supported remote from said end by link lever means for and arranged for holding said spokes in radially retracted and in radially extended positions.

3. A device according to claim 2 wherein said link lever means of each umbrella means are coupled together via a respective annular member disposed around said central axial support and axially displacable therelong.

4. A device according to claim 3 wherin an elongate tube extends around the central axial support between

the umbrella means and a remote handle means provided with respective control means for said first and second unbrella means.

5. A device according to claim 4 wherein said control means are displacable relative to the main body of said handle means and connected to respective ones of said annular members.

6. A device according to any one of claim 1 to 5 wherein said spokes provided with cutting edges.

7. A device according to any one of calims 1 to 6 wherein said spokes are formed and arranged for positively engaging tumour tissue.

8. A device according to any one of claims 1 to 8 wherein each said umbrella means has an elongate Bowden -cable type control means formed and arranged for remotely expanding said umbrella means.

9. A device according to any onme of claims 1 to 8 which device includes a diathermy electrical power supply.

10. A device according to claim 1 for use in tunnelling through large bowel obstructions.

11. A method of tunnelling through large bowel obstructions comprising the steps of:
providing a diathermy tunnelling umbrella device according to claim 9;
advancing the tip into said obstruction with diathermic cutting;
radially expanding at least one said umbrella means with radial diathermic cutting of the spokes into said

obstruction; and

rotating the expanded umbrella means with annular diathermic cutting of the spokes into said obstruction.

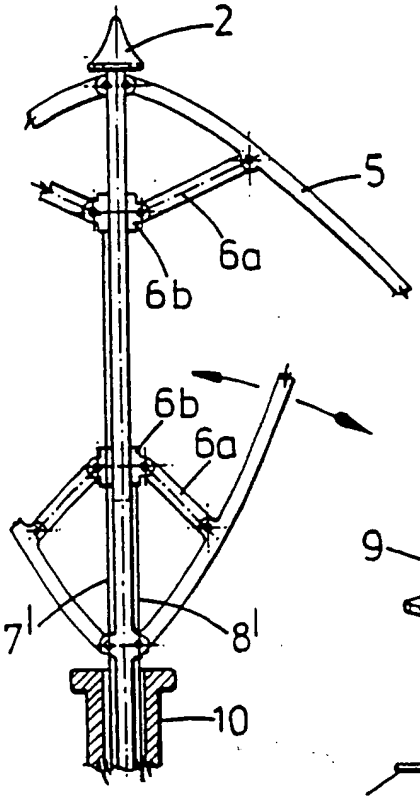


FIG. 2

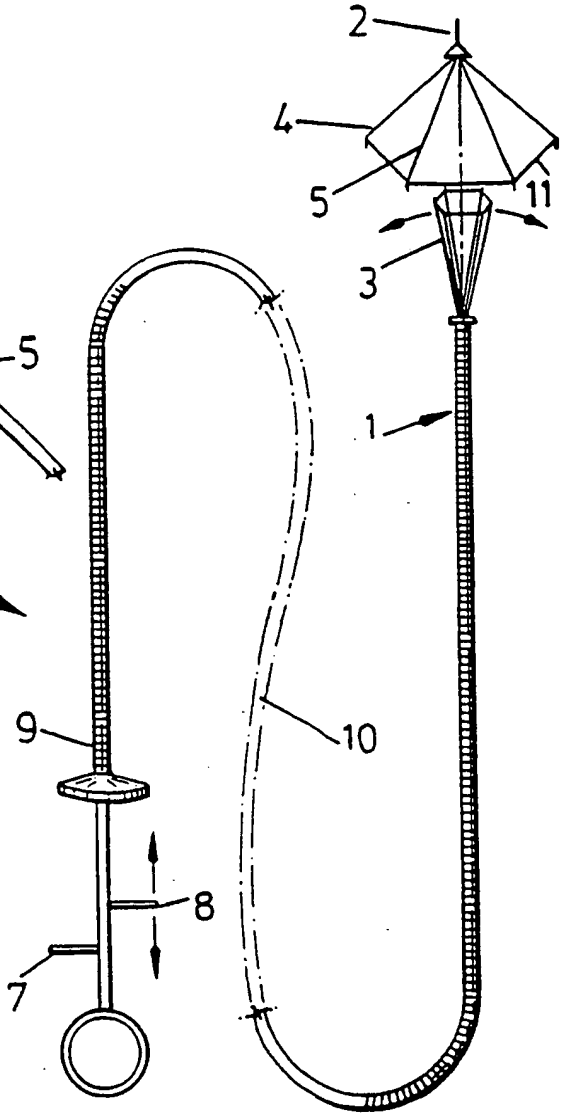


FIG. 1

FIG.3

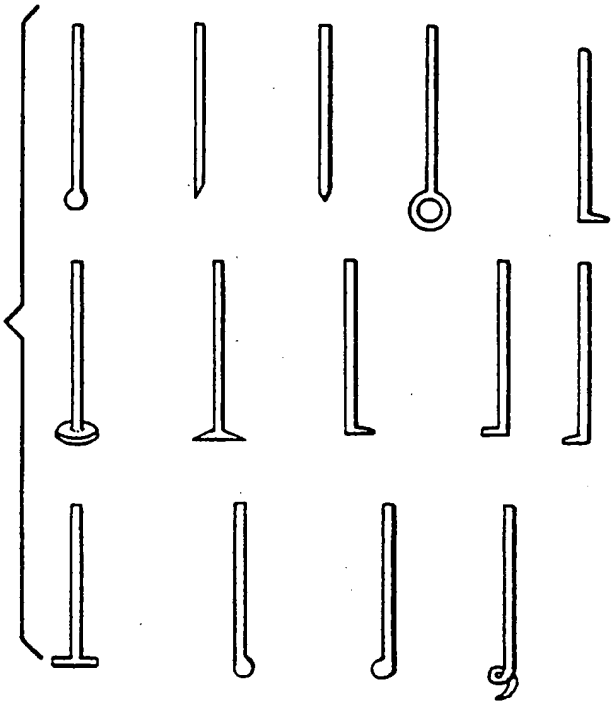


FIG.4

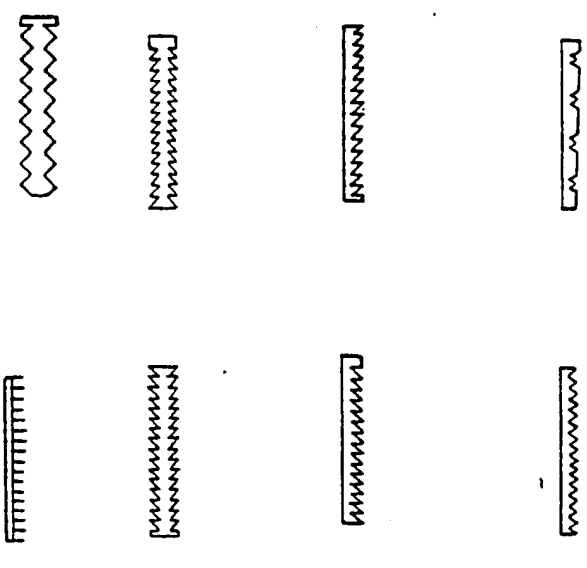
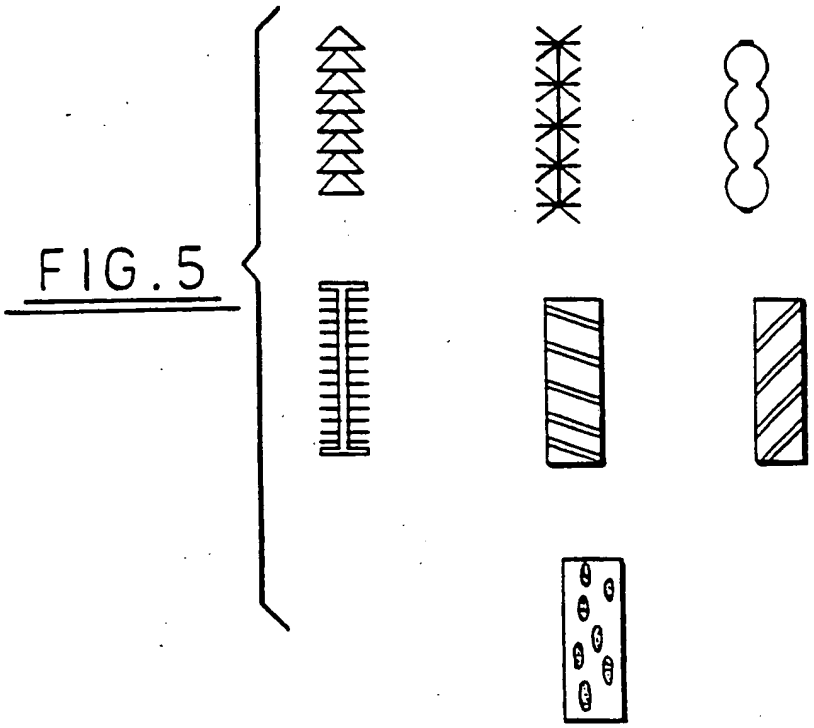


FIG.5



A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39 A61B17/22 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 154 724 (ANDREWS) 13 October 1992 see abstract; figure 11	1
A	US,A,4 976 711 (PARINS) 11 December 1990 see column 7, paragraph 2; figures 6,8,9	1
A	US,A,3 874 388 (KING) 1 April 1975 see abstract; figure 9F	1
A	EP,A,0 189 329 (FISCHELL) 30 July 1986	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 December 1994	23. 12. 94

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Barton, S

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

national application No.
PCT/GB94/01537

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 11
because they relate to subject matter not required to be searched by this Authority, namely:
see Rule 39.1 (iv) PCT

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-5154724	13-10-92	NONE	
US-A-4976711	11-12-90	US-A- 5078717	07-01-92
		US-A- 5057107	15-10-91
		US-A- 5125928	30-06-92
US-A-3874388	01-04-75	NONE	
EP-A-0189329	30-07-86	NONE	